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Dated: August 18, 2004

Signature:

Shawn P. Foley  
(Shawn P. Foley)

Docket No.:  
CELLTH 3.0-003 CONT CONT III  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Warrell et al.

Application No.: 10/759,616

Group Art Unit: 1616

Filed: January 16, 2004

Examiner: A. N. Pryor

For: **PROCESS FOR PRODUCING ARSENIC  
TRIOXIDE FORMULATIONS AND  
METHODS FOR TREATING CANCER USING  
ARSENIC TRIOXIDE OR MELARSOPROL**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REQUEST FOR CONSIDERATION OF INFORMATION UNDER 37 CFR § 1.97 (C)**

Dear Sir:

It is respectfully requested that the references cited in the enclosed form be considered pursuant to 37 C.F.R. § 1.97(c). Please charge Deposit Account No. 12-1095 in the amount of \$180.00 pursuant to 37 C.F.R. § 1.17(p). In the event that any additional fee is due in connection with the present request, the same should be charged to our Deposit Account No. 12-1095.

Dated: August 18, 2004

Respectfully submitted,

By Shawn P. Foley  
Shawn P. Foley  
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**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

It is respectfully requested that the references listed on the enclosed form be made of record and considered with respect to the above-referenced U.S. patent application. A copy of each reference was of record in United States Patent 6,723,351, the benefit of which is claimed under §120. Submission of the present Information Disclosure Statement should not be taken as an admission that the cited references are legally available prior art or that the same are pertinent or material.

In the event that any fee is due in connection with the present Information Disclosure Statement, the Commissioner is hereby authorized to charge the same to our Deposit Account

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Application No.: 10/759,616

Docket No.: CELLTH 3.0-003 CONT CONT III

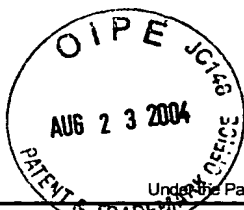
No. 12-1095.

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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>	
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		Filing Date	January 16, 2004
		First Named Inventor	Raymond P. Warrell, Jr.
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		Examiner Name	A. N. Pryor
		Attorney Docket Number	CELLTH 3.0-003 CONT CONT III
Sheet	1	of	5

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA**	US-132,275-B1	10-15-1872	Gettings	
	AB**	US-232,807	10-05-1886	Dennett	
	AC**	US-3,700,498	10-24-1972	Kanazawa et al.	
	AD**	US-4,497,780	02-05-1985	Barin et al.	
	AE**	US-5,759,837	06-02-1998	Kuhajda et al.	
	AF**	US-2002/0183385	12-05-2002	Ellison et al.	
	AG**	US-6,720,011	04-13-2004	Zhang, Ting-Dong	
	AH**	US-6,770,304	08-03-2004	Warrell et al.	
	AI**	US-2003/0099719	05/2003	Warrell et al.	
	AJ**	US-6,723,351	04-20-2004	Warrell et al.	
	AK**	US-6,773,792	05-11-2004	Lu	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	BA	JP-51-88620	03-08-1976			
	BB	WO-95/01789	01-19-1995			
	BC	CN-1133725	10-23-1996			
	BD	CN-1131037	09-18-1996			
	BE	CN-1122700	05-22-1996			
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	BJ	CN-1079391	12-15-1993			
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	BL	FR-2 539 993	03-31-1994			
	BM	DE-43 17 331	12-01-1994			
	BN	WO-95/22336	08-24-1995			
	BO	LV-11667	06-20-1997			
	BP	WO-94/02108	02-03-1994			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*\*CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	CUTLER et al., Article IV, American Journal of the Medical Sciences, pp. 74-84, January 1878	
	CB	FORKNER et al., "Arsenic as a therapeutic agent in chronic myelogeneous leukemia", Jour.	
Examiner Signature			Date Considered

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				Art Unit	1616
				Examiner Name	A. N. Pryor
Sheet	2	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT III

		A.M.A. 97(1):3-5, 1931	
	CC	STEPHENS, et al., "The therapeutic effect of solution of potassium arsenite in chronic myelogenous leukemia", University of Rochester, pp. 1488-1502, 1936	
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	CG	MONFARDINI et al., "Survival in chronic myelogenous leukemia: influence of treatment and extent of disease at diagnosis", Cancer 31: 492-501, 1973	
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	CI	ISHINISHI, et al., "Study on Chronic Toxicity of Arsenic Trioxide in Rats with Special Reference to the Liver Damages", Fukuoka Acta Medicine, 71:27, 1980	
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	CO	PERSHAGEN et al., "On the Pulmonary Tumorigenicity of Arsenic Trisulfide and Calcium Arsenate in Hamsters", Cancer Letters, 27:99-104, 1985	
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	CR	LEE et al., "Induction of Gene Amplification by Arsenic", Science, 241: 79-81, 1988	
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	CT	SUN, HONGDE et al., "32 Cases of Acute Early Granulocytic Leukemia Treated with Ai-Ling No. 1 in Combination with Chinese Medical Practice of Pattern Identification", Zhongguo Zhongxiyi Jiehe Zazhi, Vol. 12(3), 170-171, 1992	
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	CY	"Inorganic Arsenic Compounds Other Than Arsenic Health and Safety Guide", Health and Safety Guide No. 70," WHO, Geneva 1992	
	CZ	"Xionghuang, Realgar", Chinese Pharmacopia (I), Guangdong Science and Technology Publishing House, China, pp. 298-299, 1995	
	CA1	AKAO et al., "Arsenic Induces Apoptosis in B-cell Leukemic Cell Lines in Vitro: Activation of Caspases and Down-regulation of Bcl-2 Protein", British J of Hematology, 102, 1055-1060, 1998 ©Blackwell Science Ltd.	
	CB1	ANDRE et al., "The PML and PML/RAR $\alpha$ Domains: From Autoimmunity to Molecular Oncology and From Retinoic Acid to Arsenic", Experimental Cell Research, 229:253-260, 1996 ©Academic Press, Inc. 1996	
	CC1	Chemical Abstract, 63-Pharmaceuticals 11:317, 111:219272j and 111:219276p, 1987-1991	

Examiner Signature		Date Considered	
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				Examiner Name	A. N. Pryor
				Attorney Docket Number	CELLTH 3.0-003 CONT CONT III
Sheet	3	of	5		

	CD1	CHEN et al., "In Vitro Studies on Cellular and Molecular Mechanisms of Arsenic Trioxide (As <sub>2</sub> O <sub>3</sub> ) in the Treatment of Acute Promyelocytic Leukemia: As <sub>2</sub> O <sub>3</sub> induces NB <sub>4</sub> Cell Apoptosis with Down Regulation of Bcl-2 Expression and Modulation of PML-RAR $\alpha$ /PML proteins", Blood 88(3): 1052-1061, Aug. 1996 .©American Society of Hematology 1996	
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	CM1	KONIG et al., "Comparative Activity of Melarsoprol and Arsenic Trioxide in Chronic B-Cell Leukemia Lines", Blood 90(2):562-570, 1997 . ©The American Society of Hematology 1997	
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	CO1	LU et al., "Effective treatment of AML-M3 (APL) and Their Remission Maintenance with Realgar: A Pilot Clinical and Laboratory Study on 38 Patients", Blood, 90 (10 Suppl. 1, part 1):416A, #1849, 1997	
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	CS1	REICHL et al., "Effect of Arsenic on Cellular Metabolism after Single or Repeated Injection in Guinea Pigs", Arch. Toxicol, Suppl. 13, p. 363-65, 1989	
	CT1	Remington's Pharmaceutical Sciences, Mack Publishing Co., Easton, PA, pp. 1570-1580, 1990	
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	CX1	TRELEAVEN et al., "Arsenic and Ayurveda", Leukemia and Lymphoma, 10:343-345, 1993	
	CY1	USP Dictionary of USAN and International Drug Names, United States Pharmacopeial Conventions, Inc., Rockville, MD p. 59, Nov. 1994.	
	CZ1	WANG et al., "Studies on Chemically Preventing Leukemia", Ghung Hua Chung Liu Tsa Chih, 11(3):207-210, 1989	
	CA2	XIANG et al., "60 Cases of Treating Acute Promyelocytic Leukemia by QINGDAI Tablet", Med. J. Chin. PLA 20(3):227-229, 1995	

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Sheet	4	of	5	Attorney Docket Number	CELLTH 3.0-003 CONT CONT III

	CB2	YUAN et al., "Research on Traditional Methods for Purifying Realgar", Chung Yao Tung Pao, 13(8):23-26, 1988	
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	CD2	ZHANG et al., "Traditional Chinese and Western Medicine in the Treatment of 27 Patients with Malignant Lymphoma," Chinese J. Oncology, 10:61-62, 1988	
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	CF2	ZHANG et al., "Treatment of Acute Promyelocytic Leukemia with Intravenous Arsenic Trioxide", Chinese J. of Hematology 17(2) 1996	
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	CH2	"Letter on Historical Facts Regarding the Development of Ai Ling No. 1 and the Clinical Use of Arsenic Trioxide in the Treatment of Acute Promyelocytic Leukemia and a Study of Its Mechanism", Heilongjiang Branch of the Chinese Medical Association, Mar. 27, 1998.	
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	CV2	SOIGNET et al., "Initial Clinical Study of a Novel Organic Arsenical, Melarsoprol, in Patients with Advanced Leukemia", Blood (W.B., Saunders, Philadelphia, PA), vol. 88, No. 10, p. 219A (ISSN: 0006-4971) (1996)	

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